

**III. In the Claims (Marked Version)**

Please amend the claims as follows:

1. (Three Times Amended) A vaccine for the prevention of *Campylobacter* colonization in animals comprising an effective amount of antiserum raised against a flagellaless *Campylobacter* strain wherein the flagellaless *Campylobacter* strain recognizes a 97 kD (+/-5 kD), a 60 kD (+/-5 kD), and a 13 kD (+/-3 kD) band on a Western Blot.

### III. Remarks

Applicants submit the following response to the Examiner's Final Rejection of April 10, 2002 with this RCE:

#### A. Rejections Under 35 USC §112

Claim 3 stands rejected under 35 USC §112, 2<sup>nd</sup> ¶ as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The Examiner maintains the position that recitation of the term R2 is not sufficient to enable the invention. Applicants respectfully request reconsideration of the rejection in light of well-established case law and in light of the art cited by the Examiner.

First, the use of the term R2 to describe a flagella-less *Campylobacter* would be well understood in the art. Reference to the article cited by the Examiner by Cathraw et al., titled "Isotype, Specificity, and Kinetics ...", Avian Diseases 38:341-349, at page 344, illustrates that the term R2 is well-known as a descriptor for an a flagellaless strain of *Campylobacter*. Likewise, the article cited by the Examiner by Wassenaar et al., titled "Inactivation of *Campylobacter jejuni* flagellin genes ...", The EMBO Journal 10:8:2055-2061, at page 2055, further illustrates that the term R2 is well-known in the art as a species of a flagellaless *Campylobacter*. Accordingly, the term is distinctly claimed and understood by those of ordinary skill in the art. No further description is required. Therefore, Applicants respectfully request reconsideration of the rejection in light of this response. The term R2 is not an arbitrary label as proposed by the Examiner in the First Office Action. The term has well recognized properties.

**B. Rejections Under 35 USC §102(b)****1. Rejection of Claims 1-2 and 9 by Blaser I**

Claim 1-2 and 9 stand rejected under 35 USC §102(b) as being anticipated by an article to Blaser et al. in a journal titled Infection Immunity, Vol. 53(1), July 1986, pp. 47-52 (hereinafter referred to as Blaser I). The Examiner states, from the first office action, that the claimed invention of Claims 1 and 2 are directed to a vaccine composition of antiserum directed to a flagellaless strain of *Campylobacter jejuni*. The Examiner further states that Claim 9 is directed to an antigen protein of *Campylobacter*. However, the Examiner then states that the term vaccine is not being read as a limitation, but rather as an intended use. Applicants previously amended the claims to specify that the claim was directed to a vaccine. Applicants used the phrase "an effective amount" in the body of the claim. Reading the preamble and the body together particularly points out that a vaccine is being claimed.

Claim 1 currently reads as follows:

"A vaccine for the prevention of *Campylobacter* colonization in animals comprising an effective amount of antiserum raised against a flagellaless *Campylobacter* strain."

In the interpretation of the meaning of a preamble, there are several possibilities. First, as the Examiner suggests, a preamble may be interpreted as an intended use. *Rowe v. Dror*, 112 F. 3d 473, 478 (Fed. Cir. 1997). However, a more succinct rule for the interpretation of a preamble is that a preamble has the import that the claims as a whole suggests for it. *Bell Comm. Res., Inc. v. Vitalink Comm., Inc.*, 55 F. 3d 615, 620 (Fed. Cir. 1995). Here, the body of the claim specifically states that an effective amount of antiserum raised against a flagellaless *Campylobacter* strain is claimed. Reading the

preamble, a vaccine, with the body clearly indicates that an effective amount of antiserum raised against a flagellaless *Campylobacter* strain is for a vaccine. The Examiner's position that an effective amount is any amount that is effective to immunoreact with flagellaless *Campylobacter* strain is not tenable when considering the entire claim, i.e., the preamble and the body of the claim together. *See Bell Comm. Res., Inc.*, 55 F. 3d at 620. When taking the import of the whole claim, the preamble does limit the claim to a vaccine.

Moreover, as the Examiner agrees, Applicants specifically claim a flagellaless strain of *Campylobacter*. The Blaser I article specifically concludes that only a flagellar protein, and thus only the strains of flagellar *Campylobacter* that produce flagellar, plays a role in cross protection between strains of different serotype. Therefore, the Blaser I article only discloses that vaccines of the flagellar type work. There is no disclosure of a flagellaless vaccine.

## 2. Rejection of Claims 1-2 by Dolby

Claims 1-2 stand rejected under 35 USC §102(b) as being anticipated by an article to Dolby et al. in a journal titled J. Hyg. Camb., Vol. 96, pp. 143-151, 1986 (hereinafter referred to as the Dolby article). The Examiner states that it is her position that the Dolby article discloses an antiserum that comprises antibodies that were effective in passively immunizing a young animal. However, the Dolby article only discloses the use of vaccines of whole cell and outer protein membrane extracts. (See p. 144, 1st ¶ under Vaccines). Moreover, the Dolby article specifically states that there is no difference between the flagellaless and the flagellaless vaccines. (See the Dolby article, pp. 146-

147). Therefore, the Dolby article specifically teaches against Applicants' invention. Applicants' invention, in an embodiment as claimed in Claims 1 and 2, is a vaccine of an effective amount of antiserum raised against a flagellaless *Campylobacter* strain that is specifically shown to be more effective than a flagellaless vaccine.

Experiment 1 on page 11 of Applicants patent application specifically illustrates that repeated daily passive immunization with serum against wild type *Campylobacter* or with unvaccinated chicken control serum had no effect on cecal colonization by wild type *Campylobacter* if compared to untreated control chickens. All three groups showed high levels of cecal colonization by *Campylobacter*. Whereas, in sharp contrast, a passive immunization with antiserum according to the invention (raised against a flagella negative mutant) resulted in elimination of wild type *Campylobacter* from the ceca.

As the instant invention pointed out, this was unexpected because the literature indicated otherwise. (See p. 12, Detailed Description of the Invention, Applicants' Application). It is clear that there has been no disclosure of Applicants' invention. The Dolby article specifically states that the flagellaless and the flagellaless strain worked the same whereas Applicants' invention illustrated that antiserum raised against a flagellaless strain of *Campylobacter* performed better as a vaccine than the flagellaless strains. Accordingly, the Dolby article does not disclose Applicants' invention. *See In re Robertson*, 19 U.S.P.Q.2d at 1951. Applicants respectfully request reconsideration of the rejection.

### 3. Rejection of Claims 1-3 by Cawthraw

Claims 1-3 stand rejected under 35 USC §102(b) as being anticipated by an article by Cawthraw et al. in a journal titled Avian Diseases, April-June, 1994, Vol.

38(2) pp. 341-349 (hereinafter referred to as the Cathraw article). It is the position of the Examiner that the Cathraw article discloses anti-*C. jejuni* IgG antibodies induced to a strain of *Campylobacter jejuni*, wherein the antibodies were administered to eggs and ultimately to young chickens. The Examiners position is then that a vaccine of antiserum containing antibodies was passively administered to young chicks in the Cathraw article. Applicants respectfully request reconsideration of the rejection.

The Cathraw article is directed towards vaccines of a flagellaless *Campylobacter* strain. In fact, the Cathraw article repeatedly states that a flagellaless is important to the ability of the *Campylobacter* to act as a vaccine (See p. 347, 2<sup>nd</sup> ¶, Col. 2; p. 347, 1<sup>st</sup> ¶, Col. 1; Abstract, last sentence). Accordingly, the Cathraw article does not disclose Applicants' invention. Applicants' invention illustrates that antiserum raised against a flagellaless strain of *Campylobacter* is a more effective vaccine than the flagellaless vaccines of the prior art. Therefore, Applicants respectfully request reconsideration.

#### 4. Rejection of Claim 9 by Kervella

Claims 9 stands rejected under 35 USC §102(b) as being anticipated by an article to Kervella et al, in a journal titled Infection Immunity, August 1993, Vol. 61(8), pp. 3440-3448 (hereinafter referred to as the Kervella article). The Examiner's position is that Kervella was raised to a 92kDa antigen of *campylobacter jejuni* and is not a *Campylobacter fetus*. Applicants respectfully request reconsideration of the rejection.

The Kervella article teaches, at most, that antiserum to P92 outer membrane protein did not inhibit the adherence of whole bacterial cells. Such disclosure is not a disclosure of Applicants' invention. From all evidence, Kervella discloses a flagellaless strain to which the antiserum is raised. Applicants' invention illustrates that antiserum

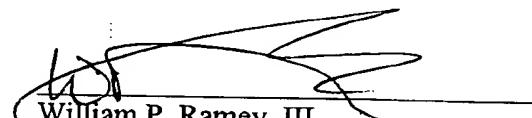
raised against a flagellaless strain of *Campylobacter* is a more effective vaccine than the flagellaless vaccines of the prior art. Accordingly, the Kervella article does not disclose Applicants' invention. Therefore, the Kervella reference does not anticipate Applicants' invention.

#### IV. Conclusion

Applicants respectfully request reconsideration of the rejections in light of this response. The application is believed in a condition for allowance and Applicants respectfully request such action. Please call the undersigned attorney for any assistance in securing allowance of this application. Applicants further respectfully request that the Examiner contact the undersigned attorney for an interview. Please charge deposit account number 02-2334 for any required fees.

Date: 7/10/02

Sincerely,



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